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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,283	10/30/2000	Benjamin Oshlack	200.1116US	1434

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DAVIDSON, DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE, 14TH FLOOR
NEW YORK, NY 10018

EXAMINER

CELSA, BENNETT M

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.

09/702,283

Applicant(s)

Oshlack et al.

Examiner

Bennett Celsa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above, claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Status of the Claims

Claims 1-41 are currently pending.

Claims 1-3 and 5-41 are under consideration.

Claim 4 is withdrawn from consideration as being directed to a nonelected invention.

NOTE: for future correspondences, the location of the present application is ART UNIT 1639.

Election/Restriction

1. Applicant's election with traverse of capsules as an oral dosage formulation and hydrocodone with the additives (e.g. Eudragit RS/RL as the "controlled release material" and stearyl alcohol) of Example 3, which applicant asserts reads on claims 1-3 and 5-41 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the search and examination of all of the subject matter is not unduly burdensome. This is not found persuasive for the reasons provided in the Restriction/Election requirement (e.g. pages 2-3 in the office action) e.g. the possible innumerable combinations of various components of different hydrocodone pharmaceutical components having different structures, chemical/biological properties, which are capable of separate manufacture and/or use; and require different and individually burdensome manual and/or computer structure and bibliographic searches in patent/nonpatent databases. The claims, as is, contain compositions which only comprise hydrocodone as a claimed ingredient and pharmaceutical parameters (delayed release profile) which preclude a meaningful and/or complete search on the merits.

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The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 16-18, 20, 27, 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite obtaining Cmax or Tmax values relative to the Cmax/Tmax provided by an “an immediate release hydrocodone reference formulation”.

However, the claim must recite the “immediate release hydrocodone reference formulation” which is critical to apprise one of ordinary skill in the art to determine what Cmax/Tmax values are within the metes and bounds of the claim; since varying the “immediate release hydrocodone reference formulation” will vary the presently claimed Cmax/Tmax parameters.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1-3 and 5-41 are rejected under 35 U.S.C. 102(a,b,e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oshlack et al. US Pat. No. 5,639,476 (6/97).

The presently claimed invention is directed to: controlled release oral dosage forms (e.g. tablets, capsule) comprising:

hydrocodone (or pharmaceutical salts) AND

“controlled release material to render said dosage form suitable for twice-a-day administration to a human patient ... said dosage form providing a therapeutic effect for at least 12 hours”. Preferred suitable “controlled release materials” include ammonio-methacrylate copolymers of acrylic/methacrylic acid esters having low content of quaternary ammonium groups (e.g. Eudragit RS and/or /RL as the “controlled release material” as disclosed in elected Example 3). The hydrocodone may be dispersed in a (multiparticulate) matrix in which the multiparticles are disposed in a pharmaceutically acceptable capsule (e.g. see claims 2, 3 and 5).

The presently claimed compositions result in *various pharmacologic parameters* including:

- a. “C₁₂/C_{max} ratio of 0.55 to 0.85” (E.g. claims 1, 36, 37);
- b. “Plasma concentration of hydrocodone of at least 8 ngm/ml at from about 2 to about 8 hours after administration ... a dosage form containing 15mg hydrochloride bitartrate” (E.g. See dependent claims 14-15);
- c. “*mean* C₁₂/C_{max} ratio of 0.55 to 0.85” (E.g. claim 38);

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- d. "rate of absorption during the time period from T_{max} to about 12 hours after oral administration ... from about 55% to about 85% of the rate of elimination during the same time period" (E.g. claim 31);
- e. "providing a T_{max} of hydrocodone in-vivo at from about 2 to about 8 hours" and "providing a C₁₂/C_{max} ratio of 0.55 to 0.85" (E.g. see claim 32; see also T_{max} values in dependent claims 11-13). See also dependent claims 27-30 for more T_{max} parameters;
- f. "after a first administration providing a C_{max} of hydrocodone which is less than about 50% of the C_{max} of an equivalent dose of an immediate release hydrocodone reference formulation" (E.g. see claim 33; dependent claims 16-17);
- g. "after a first administration providing a time to 80% mean C_{max} which is about 90% to about 110% of the time to 80% mean C_{max} of an equivalent dose of an immediate release hydrocodone reference formulation" (E.g. see claim 34; dependent claim 18); or "80% mean C_{max} of hydrocodone from about .5 to about 1.5 hours (e.g. see dependent claim 19; see also dependent claims 21-26 for variations thereof; "a 90% mean C_{max} which is about 150% to about 250% of the time to 90% C_{max} of an equivalent dose of immediate release hydrocodone reference formulation" (e.g. see dependent claim 20); "a 90% mean C_{max} of hydrocodone from about 1.5 to about 2.5 hours" (and variations thereof: see e.g. dependent claims 21--22)
- h. "T_{max} of about 2 mg/hr to about 4 mg/hr", "a mean in-vivo absorption rate from T_{max} to about 12 hours after administration which is from about 0.08 mg/hr to about 0.4 mg/hr" ... "based

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on oral administration of a dosage form containing 15mg hydrocodone bitartrate". (E.g. see claim 35);

I. "An in vitro release of at least 18% to about 42.5% by weight of the hydrocodone or salt from the dosage form at one hour ... " (E.g. see claim 39);

j. "Dissolution rate in vitro" (determined by USP Paddle/Basket method at 100 rpm in 900 ml aqueous buffer at a pH of 1.2 or 7.5 at 37 degrees celsius) of:

from about 25 to about 65% ... after 2hrs;

from about 45 to about 85% ... after 4hrs; and

greater than about 60% ... after 8 hrs (See E.g. claims 40 and 41; and dependent claims 7-10), respectively).

The Oshlack et al. Patent reference teaches controlled release oral dosage forms (e.g. tablets, capsule) comprising:

OPIOID analgesics (or pharmaceutical salts: e.g. see patent claims 1 and 6) AND

"controlled release material to render said dosage form suitable for twice-a-day administration to a human patient e.g. "said dosage form providing a therapeutic effect for at least 12 hours" (e.g. see patent claim 3). Oshlack et al. teach "controlled release materials" within the scope of the presently claimed invention which include ammonio-methacrylate copolymers of acrylic/methacrylic acid esters having low content of quaternary ammonium groups. E.g. patent claim 1; col. 4-5; 7-12 with Eudragit RS and/or /RL as the "controlled release material" being most preferred (e.g. see col. 9 ; and patent examples). . The opioid analgesic may be dispersed in

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a (multiparticulate) matrix in which the multiparticles are disposed in a pharmaceutically acceptable capsule (e.g. examples; patent claim 4). The Oshlack et al. Teaching of opioid analgesics as the most preferred active agent (e.g. see examples and patent claims) with the preferred opioid analgesics comprising less than 15 members, one of which is hydrocodone (e.g. see patent claim 6) would render the selection of hydrocodone by one of ordinary skill in the art immediately envisages (e.g. anticipates), or alternatively obvious; thus arriving at compositions containing ingredients within the scope of the presently claimed invention. E.g. see *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); MPEP 2131.02. The Oshlack et al. reference compositions further discloses controlled release profiles (e.g. see col 4, particularly lines 40-60; col. 11-12; alterable by changing resin concentrations see col. 10 and 13); and methods of manufacture (e.g. of multiparticles: col. 13-16) which are clearly within the scope of the presently claimed invention (e.g. compare with present specification).

Accordingly, the Oshlack et al. reference anticipates or alternatively renders obvious compositions (and methods of making and use) within the scope of the presently claimed invention; in which the resulting compositions *MUST inherently possess the various pharmacologic parameters (e.g. a. to j. Above)* as presently claimed. The patent office lacks the necessary facilities to make comparisons between prior art and presently claimed compositions.

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General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)

January 3, 2003

BENNETT CELSA
PRIMARY EXAMINER


